

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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PFIZER INC., WARNER-LAMBERT  
COMPANY LLC, C.P. PHARMACEUTICALS  
INTERNATIONAL C.V. and  
NORTHWESTERN UNIVERSITY,

Plaintiffs,

v.

LUPIN LTD. and  
LUPIN PHARMACEUTICALS, INC.,

Defendants.

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C. A. No. 09-309-GMS

**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS  
OF DEFENDANTS LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.**

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), by and through their attorneys, respond to each of the numbered paragraphs in the Amended Complaint by plaintiffs Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V. (“collectively Pfizer”), and Northwestern University (“Northwestern,” and together with Pfizer, “Plaintiffs”), as follows:

**Nature of the Action**

1. Lupin admits that this action arises under the patent laws of the United States and that the Amended Complaint alleges infringement of U.S. Patent Nos. 6,197,819 (“the ’819 patent”) and 5,563,175 (“the ’175 patent”). Lupin further admits that Lupin Ltd. submitted ANDA No. 91-040 to the U.S. Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j), in order to obtain approval to market Pregabalin (equivalent to 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg Pregabalin) Capsules (“Lupin’s Pregabalin drug

products”) in the United States before the expiration of the ’819 and ’175 patents. Lupin denies the remaining allegations in paragraph 1 of the Amended Complaint.

**The Parties**

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Amended Complaint and, therefore, denies them.

3. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Amended Complaint and, therefore, denies them.

4. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Amended Complaint and, therefore, denies them.

5. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Amended Complaint and, therefore, denies them.

6. Lupin Ltd. admits that it is a company organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Lupin Ltd. admits that it is in the business of making and selling generic pharmaceutical products. Lupin denies the remaining allegations of paragraph 6 of the Amended Complaint.

7. Lupin Pharmaceuticals, Inc. admits that it is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert Street, Suite 2150, Baltimore, Maryland. Lupin Pharmaceuticals, Inc. admits that it is in the business of selling and distributing generic pharmaceutical products and that it markets, distributes and sells generic pharmaceutical products throughout the United States. Lupin denies the remaining allegations of paragraph 7 of the Amended Complaint.

**Jurisdiction and Venue**

8. Lupin admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) with respect to the counts for infringement of the '819 and '175 patents. Lupin denies the remaining allegations of paragraph 8 of the Amended Complaint.

9. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals, Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 9 of the Amended Complaint.

10. For the purposes of this action only, Lupin does not contest venue in this judicial district and otherwise denies the allegations of paragraph 10 of the Amended Complaint.

**The Patents-in-Suit**

11. Lupin admits that the '819 patent was issued by the U.S. Patent and Trademark Office ("USPTO") on March 6, 2001, is entitled "Gamma Amino Butyric Acid Analogs And Optical Isomers," is assigned on its face to Northwestern University, and what purports to be a copy of the '819 patent is attached to the Amended Complaint as Exhibit A. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 of the Amended Complaint and, therefore, denies them.

12. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Amended Complaint and, therefore, denies them.

13. Lupin admits that the '175 patent was issued by the U.S. Patent and Trademark Office ("USPTO") on October 8, 1996, is entitled "GABA And L-Glutamic Acid Analogs For Antiseizure Treatment," is assigned on its face to Northwestern University and Warner-Lambert Company, and what purports to be a copy of the '175 patent is attached to the Amended Complaint as Exhibit B. Lupin is without knowledge or information sufficient to form a belief

as to the truth of the remaining allegations in paragraph 13 of the Amended Complaint and, therefore, denies them.

14. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Amended Complaint and, therefore, denies them.

**Lyrice®**

15. Lupin admits that the FDA publication entitled “Approved Drug Products With Therapeutic Equivalence Evaluations” (“the Orange Book”) lists “CP Pharms” as the applicant of NDA No. 21-446 for LYRICA®, the latter being described as a “Capsule, Oral,” and that the dosage strengths listed in the Orange Book for LYRICA® include 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg. Lupin is without sufficient knowledge or information as to the truth of the remaining allegations in paragraph 15 of the Amended Complaint and, therefore, denies them.

16. Lupin admits that the '175 and '819 patents are listed in the Patent and Exclusivity Information section of the Orange Book in connection with NDA No. 21-446. Lupin is without sufficient knowledge or information as to the truth of the remaining allegations in paragraph 16 of the Amended Complaint and, therefore, denies them.

**Lupin's ANDA**

17. Lupin admits that Lupin Ltd. (not Lupin Pharmaceuticals, Inc.) submitted ANDA No. 91-040 to the FDA, pursuant to 21 U.S.C. § 355(j), in order to obtain approval to market Pregabalin (equivalent to 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg Pregabalin) Capsules (“Lupin’s Pregabalin drug products”). Lupin denies the remaining allegations in paragraph 17 of the Amended Complaint.

18. Lupin admits that ANDA No. 91-040 refers to NDA No. 21-446 and further admits that ANDA No. 91-040 contains data establishing the bioequivalence of Lupin’s

Pregabalin drug products to LYRICA®. Lupin denies the remaining allegations in paragraph 18 of the Amended Complaint.

19. Lupin admits that on March 23, 2009, Lupin Ltd. (not Lupin Pharmaceuticals, Inc.) sent letters to C.P. Pharmaceuticals International C.V., Northwestern University, Warner Lambert Company, Kohn & Associates, PLLC, Pfizer Inc., and Warner-Lambert Company LLC informing them that Lupin Ltd., on December 30, 2008, submitted ANDA No. 91-040 to the FDA, and that the ANDA contains a Paragraph IV Certification with respect to the '175 patent and the '819 patent, which certification asserts that these two patents are invalid and/or will not be infringed by Lupin's Pregabalin drug products. Lupin denies the remaining allegations in paragraph 19 of the Amended Complaint.

**Count for Infringement of U.S. Patent No. 6,197,819**

20. Lupin incorporates by reference its responses to paragraphs 1-19 of the Amended Complaint as if fully set forth herein.

21. Lupin denies the allegations in paragraph 21 of the Amended Complaint.

22. Lupin denies the allegations in paragraph 22 of the Amended Complaint.

23. Lupin denies the allegations in paragraph 23 of the Amended Complaint.

24. Lupin denies the allegations in paragraph 24 of the Amended Complaint.

25. Lupin denies the allegations in paragraph 25 of the Amended Complaint.

**Count for Infringement of U.S. Patent No. 5,563,175**

26. Lupin incorporates by reference its responses to paragraphs 1-25 of the Amended Complaint as if fully set forth herein.

27. Lupin denies the allegations in paragraph 27 of the Amended Complaint.

28. Lupin denies the allegations in paragraph 28 of the Amended Complaint.

29. Lupin denies the allegations in paragraph 29 of the Amended Complaint.

30. Lupin denies the allegations in paragraph 30 of the Amended Complaint.

31. Lupin denies the allegations in paragraph 31 of the Amended Complaint.

**Prayer For Relief**

32. Lupin denies that plaintiffs are entitled to the judgment and relief requested in the Prayer for Relief set forth in the Amended Complaint.

**Affirmative and Separate Defenses**

Without prejudice to the denials set forth in its responses to paragraphs 1 through 32 of the Amended Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

**First Affirmative and Separate Defense  
(Noninfringement of the '175 and '819 Patents)**

33. Lupin's Pregabalin drug products that are the subject of Lupin Ltd.'s ANDA No. 91-040 do not and will not infringe any valid and enforceable claim of the '175 patent.

34. Lupin's Pregabalin drug products that are the subject of Lupin Ltd.'s ANDA No. 91-040 do not and will not infringe any valid and enforceable claim of the '819 patent.

**Second Affirmative and Separate Defense  
(Invalidity of the '175 and '819)**

35. The '175 patent, and claim 1 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

36. The '819 patent, and each of the claims 1 through 4 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

**Counterclaims**

37. Defendant/Counterclaim-Plaintiffs Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin") bring the following Counterclaims against Plaintiffs/Counterclaim-Defendants Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V. and Northwestern

University (collectively, "Plaintiffs") for a declaratory judgment that the '175 and '819 patents are invalid and/or not infringed by the Lupin's Pregabalin drug products that are the subject of ANDA No. 91-040.

**The Parties**

38. Counterclaim-Plaintiff Lupin Ltd. is corporation organized and existing under the laws of India having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

39. Counterclaim-Plaintiff Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert Street, Suite 2150, Baltimore, Maryland.

40. Upon information and belief, Counterclaim-Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42<sup>nd</sup> Street, New York, New York.

41. Upon information and belief, Counterclaim-Defendant Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42<sup>nd</sup> Street, New York, New York.

42. Upon information and belief, Counterclaim-Defendant C.P. Pharmaceuticals International C.V. is a limited partnership organized and existing under the laws of the Netherlands and having a principal place of business at 235 East 42<sup>nd</sup> Street, New York, New York.

43. Upon information and belief, Counterclaim-Defendant Northwestern University is an Illinois corporation and having its principal place of business at 633 Clark Street, Evanston, Illinois.

**Jurisdiction and Venue**

44. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin and Counterclaim Defendants Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V., and Northwestern University arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

45. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391, 1400(b), and by Counterclaim-Defendants' choice of forum.

**First Counterclaim  
(Declaration of Noninfringement of the '175 and '819 Patents)**

46. Lupin incorporates by reference the allegations set forth in paragraphs 37 through 45 of the Counterclaims as if fully set forth herein.

47. Counterclaim Defendants Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V., and Northwestern University have filed a civil action in this judicial district against Lupin for allegedly infringing the '175 and '819 patents. There is an actual case or controversy between Lupin and Counterclaim Defendants Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V., and Northwestern University concerning the alleged infringement of the '175 and '819 patents by Lupin's Pregabalin drug products described in Lupin Ltd.'s ANDA No. 91-040.

48. Lupin does not infringe any valid and enforceable claim of the '175 patent.

49. Lupin does not infringe any valid and enforceable claim of the '819 patent.

**Second Counterclaim  
(Declaration of Invalidity of the '175 and '819 Patents)**

50. Lupin incorporates by reference the allegations set forth in paragraphs 37 through 45 of the Counterclaims as if fully set forth herein.



51. There is an actual case or controversy as to the validity of claim 1 of the '175 patent and claims 1 through 4 of the '819 patent.

52. The '175 patent, including claim 1 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

53. The '819 patent, including claims 1 through 4 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

**Third Counterclaim**  
**(Declaration of Invalidity of Patent Term Extension)**

54. Lupin incorporates by reference the allegations set forth in paragraphs 37 through 45 of the Counterclaims as if fully set forth herein.

55. The '819 patent was granted a patent term extension under 35 U.S.C. § 156.

56. The patent term extension granted to the '819 patent fails to meet one or more of the requirements of 35 U.S.C. § 156 and is thus invalid.

**Fourth Counterclaim**  
**(Exceptional Case)**

57. Lupin incorporates by reference the allegations set forth in paragraphs 37 through 56 of the Counterclaims as if fully set forth herein.

58. Prior to filing the Complaint and Amended Complaint in this action, Lupin disclosed to Plaintiffs the factual and legal bases underlying its invalidity and noninfringement contentions in a notice letter dated March 23, 2009, and offered Plaintiffs access to Lupin Ltd.'s ANDA No. 91-040 which disclosed the formulation of Lupin's Pregabalin drug products, methods for their preparation and draft (proposed) package label. At no time prior to filing the Complaint or the Amended Complaint did Plaintiffs accept Lupin's offer of access to ANDA No. 91-040 or request any information from Lupin concerning ANDA No. 91-040 or Lupin's Pregabalin drug products. Despite having this information and the offer of access to Lupin

Ltd.'s ANDA No. 91-040, Plaintiffs failed to make a good faith inquiry into the factual bases for its allegations against Lupin for infringement of the '175 and '819 patents.

59. At the time Plaintiffs filed the Complaint and the Amended Complaint, Plaintiffs had no objectively reasonable basis for asserting the '175 and '819 patents against Lupin.

60. This is an "exceptional case" within the meaning of 35 U.S.C. § 285.

**Prayer for Relief**

WHEREFORE, Lupin prays that this Court enters judgment against Plaintiffs:

- A. Declaring that the claims of the '175 and/or '819 patents are not and would not be infringed by Lupin;
- B. Declaring that the claims of the '175 and/or '819 patents are invalid;
- C. Declaring that the patent term extension of the '819 patent is invalid;
- D. Determining that, under 35 U.S.C. § 285, this is an "exceptional case" and awarding Lupin its attorneys' fees in this action;
- E. Awarding Lupin its costs and expenses incurred in this action; and
- F. Awarding Lupin such other and further relief as the Court may deem proper.

May 26, 2009

BAYARD, P.A.

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